COVID-19 Update: Serological Tests

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What is a serological test?

Serological tests measure the level of antibodies or proteins present in the blood when the body is responding to a specific infection, like COVID-19. In other words, the test detects the body's immune response to the infection caused by the virus rather than detecting the virus itself.

In the early days of an infection when the body's immune response is still building, antibodies may not be detected. This limits the test's effectiveness for diagnosing COVID-19 and why it should not be used as the sole basis to diagnose COVID-19.

Why is a serological test important?

Serological tests can play a critical role in the fight against COVID-19 by helping healthcare professionals to identify individuals who have overcome an infection in the past and have developed an immune response.

In the future, this may potentially be used to help determine, together with other clinical data, that such individuals are no longer susceptible to infection and can return to work.

In addition, these test results can aid in determining who may donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19.

In March, the FDA issued a policy to allow developers of certain serological tests to begin to market or use their tests once they have performed the appropriate evaluation to determine that their tests are accurate and reliable.

This includes allowing developers to market their tests without prior FDA review if certain conditions outlined in the guidance document are met. The FDA issued this policy to allow early patient access to certain serological tests with the understanding that the FDA has not reviewed and authorized them.